



NEW STUDY SHOWS REDUCED HOSPITAL STAY & IMPROVED PATIENT OUTCOMES IN PEDIATRIC PATIENTS TREATED WITH OMNIGUIDE'S® FLEXIBLE CO₂ LASER FIBERS FOR OBSTRUCTIVE AIRWAY FIBROMA

The BeamPath™ CO₂ Laser Fiber was used to resect obstructive airway fibromas in children and was compared to an open surgical modality, as well as to “line-of-sight” articulated-arm CO₂ lasers. Results show significant reduction in hospital stay vs. open excision and fewer follow-up procedures vs. the line-of-sight CO₂ laser system.

Cambridge, Mass.—Aug 1, 2008—[OmniGuide, Inc.](#), the developer of the first and only flexible CO₂ laser scalpel, announced today the results of a study comparing three treatment options—external surgical excision, line-of-sight CO₂ laser and the [BeamPath™](#) flexible CO₂ laser fiber. Thirty pediatric patients with an average age of three years underwent procedures to remove suprastomal tracheal fibromas in their windpipe. The study compared operating-room time, hospitalization time, need for follow-up procedures, and the success rate of immediate post-operative removal of a tracheal tube, a process called decannulation. The study, led by Jerome Thompson, M.D., MBA, Chairman, Department of Otolaryngology, Head and Neck Surgery at University of Tennessee Health Science Center, was presented recently at the Combined Otolaryngology Spring Meetings (COSM-2008) in Orlando, FL.

“The pediatric suprastomal fibroma study demonstrated that the use of a flexible CO₂ laser fiber improves quality of care and clinical outcomes on several levels,” said Dr. Thompson. “The rate of immediate removal of the tracheal tube was four times greater in the flexible fiber group than the external excision group and two times greater than the line-of-sight CO₂ laser group. Additionally, half of the patients who underwent treatment with the fiberoptic CO₂ laser carrier had already undergone external excision prior and had experienced recurrence. After then undergoing treatment with the fiberoptic CO₂ laser fiber, 3 of these 5 patients had their tracheal tube removed immediately and did not experience recurrence of fibroma. Lastly, while the external excision patients are always monitored overnight in the hospital, the endoscopic procedures were performed on an outpatient basis and the children were usually sent home after 3 to 4 hours.”

Specific study results include:

- **Decreased Need for Follow-up Procedures**— 60% of patients treated by external excision and 70% of patients treated with a line-of-sight CO₂ laser required additional procedures to fully remove the lesion, compared with only 30% of patients treated with BeamPath™ fiber. Using the BeamPath™, surgeons can reach deeper into the airway and more closely approximate tissue, allowing them to dissect

fibroma from the tracheal wall more easily. This feature is thought to reduce the need for further procedures.

- **Increased Rate of Postoperative Decannulation**— When suprastomal fibroma is sufficiently removed, clinicians can proceed with postoperative decannulation. 40% of patients treated with the BeamPath™ fiber proceeded to immediate postoperative decannulation compared with only 20% of the line-of-sight CO₂ laser and 10% of the external excision trial arms.
- **Hospitalization time** — Patients treated with the BeamPath™ fiber and traditional CO₂ laser had similar postoperative hospital stays of approximately 3 to 4 hours, compared with 24 hours for external excisions procedures. Shorter procedure and hospitalization times translate into reduced healthcare costs.

“Pediatric airway conditions present acute challenges to the surgeon due to the fragile anatomy of the airway in children. Dr. Thompson's important study establishes the superiority of OmniGuide's precision surgical fibers for the treatment of suprastomal tracheal fibromas. We are working to ensure that our precision fiber optic scalpels are available to pediatric surgeons nationwide.” said Yoel Fink, president and CEO of OmniGuide. “BeamPath™ precision flexible CO₂ laser fibers are enabling ENT surgeons to conduct new minimally-invasive procedures and helping improve the quality of healthcare for patients.”

About BeamPath™ Precision Optical Scalpels

Surgeons have used CO₂ lasers for more than 30 years due to the high-degree of precision cutting capabilities. However, CO₂ lasers were previously limited to “line-of-sight” procedures with no flexible delivery system available. OmniGuide’s BeamPath™ fiber is based on breakthrough fiber technology developed at MIT, published in *Nature* and *Science* magazines. This technology has enabled OmniGuide to manufacture the world’s first flexible fibers for CO₂ laser surgery. BeamPath™ fibers empower surgeons to perform delicate cutting and coagulation with minimal thermal tissue damage and maneuverability, a major advantage over traditional line-of-sight CO₂ lasers. Since their initial launch, BeamPath™ fibers have been used successfully in more than 4,000 surgical procedures in the fields of Laryngology, Head & Neck Surgery, Otolaryngology, Gynecology, Neurosurgery and Spine Surgery.

About OmniGuide, Inc.

OmniGuide, Inc., is the worldwide leader in precision optical scalpels for minimally invasive surgery. OmniGuide CO₂ laser fibers are clinically targeted disposable optical scalpels optimized for specific surgical procedures. The company recently introduced a line of fiber-enabled, portable, low-cost CO₂ lasers for use in operating rooms and surgical suites. The company designs and manufactures its fiber products in Cambridge, Mass. based on multi-material photonic bandgap fiber technology exclusively licensed from MIT. The company currently distributes its products in the U.S. and Europe. OmniGuide is committed to developing products that improve and expand surgical treatment options, enhance clinical outcomes, and reduce treatment complexity and cost.

Additional information about OmniGuide can be found at www.omni-guide.com

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Management of suprastomal tracheal fibroma: Introduction of a new technique and comparison with other techniques.

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OBJECTIVE: Compare the operative time, hospitalization time, need for further treatments, and incidence of immediate postoperative decannulation with use of one of three methods for removal of suprastomal tracheal fibroma.

INTRODUCTION:

Suprastomal tracheal fibroma is a common cause of failure to decannulate following pediatric tracheostomy. These fibromas are felt to be secondary to friction from the tracheostomy tube on the anterior tracheal wall. Because these lesions obstruct the trachea, it is necessary to remove them prior to decannulation. Various methods have been described for the management of these obstructing tracheal lesions. Surgical removal of a suprastomal fibroma requires removal of part of the anterior tracheal wall. Microlaryngoscopic CO2 laser therapy is widely used for lesions down to the subglottis, but there is frequent difficulty in accessing the distal trachea. Rigid bronchoscopy with the fiberoptic KTP or Nd-YAG laser system has an increased risk of airway fire, airway perforation, and massive hemoptysis. Until recently it was thought that the CO2 laser could not be transmitted through a fiberoptic cable secondary to being absorbed by the media. This was a distinct disadvantage to the surgeon in having to use an articulated arm with the CO2 laser. One company has produced a hollow core guide fiber for the CO2 laser that can be advanced to better approximate targeted tissues and minimize thermal spread. This has been used in patients with papillomas, head and neck cancers, and otosclerosis. This study compared two commonly used methods of suprastomal fibroma removal to the new CO2 laser that is brought into near-contact with the tissue of a suprastomal fibroma in pediatric patients using a fiber and modified carrier.

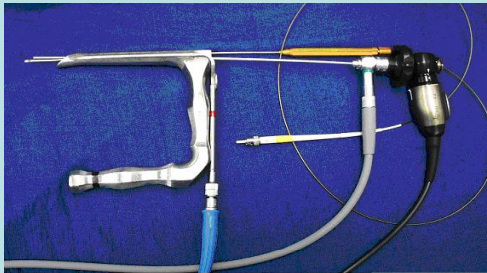


Figure 1: The CO2 laser fiber (150 cm length, 1.2 mm OD, 240 μm spot size) and the carrier inside the Dedo laryngoscope. The Hopkins zero degree 2 mm telescope is also placed inside the laryngoscope.



Figure 2: Close-up view of the CO2 laser fiber tip and carrier

STUDY DESIGN: We performed a retrospective chart review of patients with suprastomal tracheal fibroma who underwent one of three methods of treatment between March 2006 and March 2008 at Lebonheur Children's Medical Center, a tertiary pediatric referral center.

SUBJECTS: The subject population includes patients that have developed suprastomal fibroma secondary to tracheostomy. The fibroma has been documented with direct laryngoscopy and bronchoscopy. These patients otherwise could be decannulated if the fibroma were removed. A total of 30 children under the age of 7 years (21M,9F) with suprastomal fibroma underwent treatment by either external excision (n=10), microlaryngoscopic CO2 laser vaporization with articulated arm and directed beam (n=10), or CO2 laser vaporization by fiberoptic laser carrier (n=10). Patients with other benign tumors of the trachea or bronchus were excluded.

OUTCOMES: Our outcome measures were the operative time, the hospitalization time following the procedure, the need for further intervention, and the incidence of immediate postoperative decannulation.

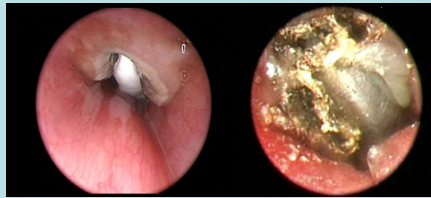


Figure 3: Anterior tracheal fibroma before and immediately after vaporization using fiberoptic CO2 laser carrier

Method of removal	Operative time (min)	Hospital time (hr)	Need for further procedures (% of patients)	Immediate postoperative decannulation (% of patients)
external excision	34.9	24	60	10
microlaryngoscopic CO2 laser with articulated arm	16.3	3.3	70	20
fiberoptic CO2 laser carrier	19.7	3.9	30	40

RESULTS: The study population included 21 males and 9 females with a mean age at treatment for suprastomal fibroma of 3 years of age. Mean operative time for external excision was 34.9 min (SD=10.2min), for microlaryngoscopic CO2 laser was 16.3 min (SD=4.8min), and for fiberoptic CO2 laser carrier was 19.3 min (SD=7.1min). Mean hospital time postoperatively for external excision was 24 hr (SD=510 min), for microlaryngoscopic CO2 laser was 3.3 hr (SD=37.7min), and for fiberoptic CO2 laser carrier was 3.9 hr (SD=46.3min). Need for additional procedures was seen in 60% of external excision procedures, 70% of microlaryngoscopic CO2 laser procedures, and in 30% of fiberoptic CO2 laser carrier procedures. Immediate postoperative decannulation was possible in 10% of the external excision group, 20% of the microlaryngoscopic CO2 laser group, and 40% of the fiberoptic CO2 laser carrier group.

DISCUSSION: The operative times and hospital times when using both the microlaryngoscopic CO2 laser and fiberoptic CO2 laser carrier were similar and were significantly less than for external excision of fibromas. However, the patient with the longest postoperative hospitalization was also the one patient who underwent external excision and was decannulated in the immediate postoperative period. The need for additional procedures was significantly less in the fiberoptic CO2 laser carrier group than both the microlaryngoscopic CO2 laser and external excision groups. The need for additional procedures was slightly higher in the microlaryngoscopic CO2 laser group than the external excision group. This was felt to be secondary to the difficulty in approximating the fibroma with the conventional laser and articulating arm. The microlaryngoscopic CO2 laser and fiberoptic CO2 laser carrier showed similar operative times and hospital times, yet the carrier resulted in fewer patients requiring additional procedures. We suspect operative times using the fiberoptic carrier will shorten as surgeons become familiar with this new technology. One advantage of the fiberoptic carrier is the ease in approximating tissues and dissecting fibromas from the tracheal wall. This characteristic is thought to contribute to the smaller rate of need for further procedures. Both the microlaryngoscopic and fiberoptic CO2 lasers show shorter hospitalization times because the external excision patients are always monitored overnight, while the former procedures are both performed on an outpatient basis. Half of the patients who underwent treatment with fiberoptic CO2 laser carrier had already undergone external excision and had experienced recurrence. After then undergoing the fiberoptic CO2 laser carrier treatment, 3 of these 5 patients were decannulated immediately postoperatively and did not experience recurrence of fibroma. In 30% of our patients who underwent microlaryngoscopic CO2 laser excision, residual untreated fibroma was noted at the time of surgery and plans were made to bring the patient back for removal of fibroma using fiberoptic carrier on the basis that the fibroma would be better accessed with the flexible carrier. The rate of immediate postoperative decannulation was four times greater in the fiberoptic carrier group than the external excision group and two times greater than the microlaryngoscopic CO2 laser group.

CONCLUSION: This study shows that the new technique of using a fiberoptic carrier for the CO2 laser to treat children with suprastomal fibroma results in a lower number of required additional procedures than two previously mentioned methods, a similar postoperative hospital stay as the conventional CO2 laser method, and a higher percentage of immediate postoperative decannulation than two previously mentioned methods.

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NEW DISCLAIMER 4/21/8: The authors have no financial conflict of interest to disclose at the time of the writing of this paper, but patent discussions are underway between OmniGuide, the University of Tennessee, and the senior author.